DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAY - 1 2002

Mr. Michael A. Pelton
Vice President
Biotech Corporation
107 Oakwood Drive
Glastonbury, Connecticut 06033

Dear Mr. Pelton:

This is in response to your letter of March 25, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Biotech Corporation is making the following claim, among others, for the product **Prostate Gold**:

"...lessen nocturnal urination and help to restore normal function...."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, in the context of other statements that make clear that the product is intended for "prostate support," suggests that it is intended to treat, prevent, or mitigate a disease, namely benign prostatic hypertrophy. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New England District Compliance, HFR-NE240

BIOTECH
CORPORATION

March 25, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: Notification of DSHEA nutritional support claim for BioTech Corporation, Inc., Prostate Gold Dietary Supplement.

The purpose of this letter is to provide notification pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act ("the Act") and 7 C.F.R. § 101.93 that BioTech Corporation, Inc. is marketing a dietary supplement that bears a statement of nutritional support as defined in section 403 (r)(6) of the Act.

The labeling for Prostate Gold bears the following statements:

"...100% natural support for men..."
"...is an essential part of health and well-being for men..."
"...lessen nocturnal urination and help to restore normal function..."
"...the ultimate in Prostate support..."

BioTech Corporation, Inc. has on file substantiation that the above statements are truthful and not misleading. To the best of my knowledge, the information contained in this notice is complete and accurate.

Sincerely,

Michael A. Pelton
Vice President

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The Nutraceutical Product Leader

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